PT Roundtable Meeting
College of NJ
February 26, 2004

Opening Remarks and Ground Rules

Stu Nagourney (SN) Purpose of the meeting: an exchange of information on the PT process.

Introduction of PT Providers

APG - Tom Coyner (TC)
ERA - Shawn Kassner (SK)
SPEX - Protocol Bill Hahn (BH)
Absolute Standards - Lance Boynton (LB)
Wibby - Chuck Wibby (CW)
NY DOH - Ken Jackson (KJ)

Basic Concepts of the PT Program

Presentation by Dr. Mike Miller (MM) of OQA

- *? Current system for calculating true values when more than one method is used?* MM - Same as the old EPA method. Everything is merged together especially in WP. In the near future the PT Board, Field of PT subcommittee will develop new equations, and will address how to split out information. We are only just beginning to collect information on individual prep methods and individual analytical methods. Once this data becomes available, the committee will reevaluate the data and process.

Individual Presentations by PT Providers on Statistics

ERA – Shawn Kassner: PowerPoint presentation
SPEX – Vanaja Silva Kumar – PowerPoint presentation
APG – Tom Coyner – PowerPoint presentation

General Question and Answer

- *? What is the lifetime of an ampule once it is opened?* It depends on the ampule. Something such as chlorine you have to do it right away. Each provider will give you an expiration date for the standard they provide and those should be carefully reviewed and followed by the laboratories.

- *? Criteria for homogeneity within a lot?* NIST and NELAC require that you prove each sample in the same lot with a 95% Confidence interval.

- *? Stability is tested over the 45-day period. How do you account for winter and summer conditions over shipping?* Wibby, NIST required them to simulate transport using an oven or refrigerator and doing the stability after it has been subjected. SPEX actually shipping samples out and back to FL and Canada then analyzed them and reported that to NIST.

- *? Do the providers have to use NJ approved analytical methods to analyze their samples?*
  APG - No. APG cannot meet NIST requirements if they use certified methods. They "tweak" methods to get lower RSDs. Absolute. – They need to be 1/3 tighter than the labs, they cant be expected to run the same purge and trap as the labs or they would never meet the criteria. Wibby – manufacturing quality control is different – they must ensure that the samples are acceptable for use for the analytical methods they are intended to cover.
  APG – if their requirements were as broad as ours, labs would be more likely to fail if the result was at the edge of the acceptance limit.

- Mary Kay Steinman – If it doesn't work for a particular method then what? APG – Reevaluate it after the results come back - Went back, split sample into two.

- *? If a lab can demonstrate a failure was due to provider issue, what does OQA do with the data?*
  RW We have the provider identify the problem and then we would not use the data for the study and would require the labs to run an additional sample.
  OQA would also evaluate the study results to see if there is a method problem, and possibly also not use the results of the study. NELAC labs can then do a quick turn around study to stay on the 6-month time frame.

- Some metals can be an issue (antimony) if the PT is not evaluated immediately, but still within the 45-day period.
  MM requested that the laboratories send documentation regarding this issue to the office and also file a complaint with the PT Provider.

Individual Presentations by PT Providers on Statistics (cont.)

Wibby Env – Chuck Wibby – PowerPoint presentation
Absolute Standards – Lance Boynton – PowerPoint presentation
NY DOH – Ken Jackson – PowerPoint presentation

General Question and Answer, cont.

- *? Why does it take more than 21 day to report the results to the labs?*
  RW - It's likely OQA is conducting an additional evaluation and asked the PT providers for more information.

- *? Is the HSV data available online?*
  ERA - If the laboratory is a participant, they can access it through the website or directly from the provider. NYDOH - their data is not on the website.

- *? What happens when you change the method to determine the results, but the laboratory has to follow the certified method?*
  SPEX - NIST conducted a method validation study and reviewed the data to ensure it was valid. Based on a review, NIST would either accept a method as is or suggest improvements. Every time you change the method it must be revalidated by the oversight body along with the limit. No one validates the soil methods however, except that the providers use the same methods for soils as they do for the WP WS to determine acceptance criteria. The methods used by the providers must be different than those used by the laboratories as the providers are held to tighter acceptance limits than the laboratories.
  Absolute as well as other providers follow ISO 17025 methodologies for all samples, so that promotes consistency.

- *? Soils samples present different problems. What are some of those?*
  KJ - They initially thought homogeneity would be an issue but it isn't. The problem they have is the matrix. You can make it as difficult or easy as you want, sand and clay present different recovery issues.

- *? Do you think there should be some standardization of the base matrix for soils?*
  Spex – The chemical formula of the soil used for the base is going to vary from provider to provider and how the soil reacts with each compound you add will vary. Mesh size of the soil can be the same but the chemical makeup of the base soil will always be different.

- *? Would it be better to find a natural soil that has contaminants of a certain type?*
  Spex - This is a good idea but you are still likely going to have to spike something into it. Predicting the performance of unknown chemicals is difficult.

- Mark Carter (MC) - ERA has investigated soil samples to assure consistency of the matrix and how it will respond to the samples. Samples are taken through the method process to ensure fit for use and adequate recoveries. He doesn't believe that if you require a certain portion of sand silt clay, and mesh size, it would resolve the problem.

- *? If you have an analyte in a matrix that typically gives low recoveries like hexavalent chromium in soil, how do you set acceptance limits for something like this?*
  APG - When something is actually spiked and the labs get nothing, you could drop those compounds out of the PT testing study, use other means to accredit them, or you could change concentration limits so that that laboratories are not testing near the detection limit.
  Wibby - You could center acceptance limits around the historical mean and evaluate the results for acceptability prior to scoring.
  Regulatory agencies need to say what their data quality objectives are for the soil samples to determine what is fit for use. Otherwise you will continue to see differences between providers for fit for use.

- *? What criteria does DEP use to accept a provider?*
  RW - OQA issues a contract out to bid, providers can elect to respond. OQA awards to the lowest qualified bidder. There are backups if there are problems with the awardee during the study.

- *? Is DEP considering letting labs pick their own provider?*
  RW - DEP already allows petitions for exemptions. As long as they are using an approved provider and the provider supplies HSV data they should be accepted.

- *? How are acceptance limits determined for non-NELAC parameters?*
  RW - They are based on historical data. Use peer review or consensus statistics. Some states will have a specified limit.

- *? Are acceptance limits symmetrical around the mean?*
  MM - They are based on the criteria document. They are generally spaced around the mean.

- *? Why are acceptance limits more toward one end of the range than the other?*
  MM - There is a general confusion with the assigned value and the predicted mean in the reports.

- *? NELAC provides a range of concentration for parameter results, is this for true value or calculated mean?*
  MM - True value.

- *? How does the PT Provider ensure that the results get to OQA?*
  RW - OQA gets emails and hard copies from the providers.

- *? Does OQA check for results before they issue a non-reporting letter to the laboratory?*
  Yes they do. They verify the submittal of data. OQA will receive reports for every laboratory PTs are ordered for whether data is reported to the provider or not.

- *? Why do expiration dates differ from one provider to another?*
  For QC samples this is sometimes a marketing issue. For required PT rounds, all providers give 45 days. Different manufacturers have different requirements based on the fitness for use for the analyte, it is not uniform. Marketing advantage can also fit in here.

- *? ISO 17025 criteria – Are things working the same worldwide with laboratory accreditation and PT?.*
  There are several PT provider oversight bodies around the world but those don't share reciprocity. Two main characteristics different from Europe, first the systems

are generally used for laboratory quality improvement not judgement, second most programs in Europe are voluntary.

- *? Can any of the providers be certified by NJ since they are not using NJ certified methods?*
  They could be certified if they chose to do so and if they could meet our criteria, even using other (site-specific manufacturing) methods.

PT Data Reporting by Laboratories (RW)

- Smaller labs are very unfamiliar with what is required on the form. Everything they need to report is on data that they receive from the OQA. An ACPL can be used to fill out the reporting form for a PT.

- Parameter codes are required to be reported for our PT providers (ex. SDW00000). This tells us parameter, method and technique; and eases the scoring and recording by OQA.

- How to report: PT data is to be reported directly to providers. Questions on reporting forms or on-line submittal forms should be directed to providers.

- Reporting online: There are several screens, until the screen tells you the screen has saved and submitted, the data will not be saved. Be careful not to close the screen too early, wait for confirmation that your results have been submitted to the provider.

- Provider evaluates results: HSV data is sent to NJDEP, then DEP gives the ok for the results to be sent to the laboratories and simultaneously to DEP. We would generate a letter based on the results, makeup schedules, etc. There is no need to call OQA at this time.

General Question and Answer cont. (RW)

- *? Is the data from the PT providers paper or electronic?*
  Both.

- *? Do all accredited parameters have a corresponding NELAC code?*
  Yes

- *? Can we have the system to have translation tables in house?*
  We cannot right now until the software is updated.

- APG – You can change any piece of information that has been submitted up until the close date of a study. So you can contact the provider for changes prior to the close

date if you realize there was a mistake. After the study closes you have to call NJDEP.

- APG – If you are going to submit data to another state you need to let the provider know prior to the study close date. They can't add them after the study closes. You don't want them to be able to request the data for another state based on whether or not they pass or fail. However, if a state calls, the provider could give them the data. The data will be flagged that it was requested after the study close date.

- Process for reviewing PT provider data. OQA has a team for each study to evaluate the data. OQA issues a detailed failure letter. If there are problems with these letters, please call OQA at this time. Labs dropping parameters is common problem here.

- Makeup studies are six months later. Purchase orders and vouchers are accepted. If you pass all is ok, if you fail it is a mandatory six month suspension for state not NELAP labs, based upon the rules. Use the 6 months to do another PT and get the data to OQA to get re-certified. You need the passing PT and a written request submitted to OQA to get re-certified.

- Data from providers is given to OQA and laboratories on the same day, FedEx. (final results)

- Providers issue OQA a draft of data so that OQA can review the data. Suspension letters are sent out based on final report not the draft.

- *? What if there is a mistake, i.e.decimal issues?* – OQA asks for raw data and a formal complaint in writing for evaluation.

- Letter from OQA should never be received prior to receipt of data from a provider by a laboratory. Sometimes OQA will require the running of a second sample.

- *NJ requires 1 PT per year and NELAC requires 2, how is this dealt with?* NELAC labs are on a 6-month schedule so if they fail the first one they would automatically get a sample every six months anyway.

Shipping and Scheduling (RW)

- There are no guidelines for shipping that OQA can issue to deal with shipping issues. Some breakage will always occur. Providers have been working with OQA on modifying shipping to resolve breakage and have provided additional samples when breakage occurs.

- Notification of shipment – OQA sends a pre-shipment letter that gives an approximate date. The actual date of receipt will always vary with providers as long as multiple providers are used. OQA will advise provider to extend this courtesy of notification of shipment routinely.

- Study start date doesn't change, and close date is 45 days later. We are working on minimizing shipping time problems. If there are problems with a shipping date, providers have moved close date to accommodate when reasons prevail.

- Repeated shipping problems should be directed to provider and OQA. When the studies occur (month they occur), this is OQAs decision.

- A laboratory expected samples a certain time and the samples showed up early (1/2 week). The lab then had problems with holding times. The provider also put the wrong holding time on the ampules. TDS 7-day holding, but other analytes had 28 day hold time. The information from provider did not make the holding times clear and distinguishable for all analytes.
  RW - There is some issue here with the shipping to the laboratory or from the provider. There are no requirements for PT Providers to notify the lab that samples are coming, it is only a courtesy. The holding time on the ampule is listed according to the parameter in the sample with the shortest holding time.

Cost of PTs (RW)

- PTs are regulatory requirements Yearly samples are required to be certified.

- NJ considering including PT costs in application fees in the future.

- Costs in our contract are those that the PT Providers bid.
  ERA - Costs for NJ PTs are affected by NJ contract requirements: setting up parameter codes, providing HSV data, getting information to NJ to review data prior to final scoring, ensure data submittal by laboratories is compliant and pass fail rates provided by NJ parameter code.

  So if we eliminated the NJ parameter code the cost would be reduced.

  How quickly the reports can go out is dependent upon PT Provider, but again they are waiting for NJ to review the data.

  JA - still does not believe how the cost could be so much higher. There is no additional testing that is done for NJ.
  Providers: The largest cost any provider has is quality control. NJ does have greater reporting and it does require greater customer service. Statistical data required for NJ is done more quickly than is done for other studies. 2 weeks rather than 3 weeks for delivery of the data.

- Mary Kay Steinman – will NJ stop looking at the HSV data at some point?. RW - Yes, there is a hope that we will stop looking at it.
  JA – In no case is it appropriate for anyone to elect to withhold the data that is needed to make regulatory decisions. NJ will never be able to completely relinquish its' authority to look at supporting HSV data that is supporting the PT Program due to the regulatory decisions that are based on the data.

- *? If oversight is performed on a more regular basis, would NJ continue to require this data for all studies all the time?*
  JA - That determination cannot be made at this time. NJ does not have the staffing to perform this review continually but believes that some spot-checking might always be desirable.

- *?, There is a price increase each year with PT providers. This price increase was greater than the rate of inflation. Where did this increase come from?* Paula Blaze: whole volume samples were a greater cost due to a shipping cost increase for whole volume. The initial contract did include increases in price for each year.
  ERA – not sure what went into the determination of the costs that are listed in the contract.

- Would there ever be a decrease?
  ERA – not sure.
  JA believes it is not impossible.

- Additional costs are incurred for the reporting of data to multiple regulatory authorities.

Whole Volume vs Ampule (RW)

- OQA decided to use whole volume because they are more like real world samples and would be a better test of laboratory ability. Need time to work out the “bugs”. Sample preparation generally involves only bringing samples up to volume.

- APG – Thought the first study in June went fairly well. Results in the first study were disappointing. Performance of labs was not as good as on the ampules which is what they expected. The December study results were significantly better for the NJ labs than for the other labs. Not sure why. Were they just better at dealing with them? Providers were providing extra volume where inadequate volume was an issue. APG is encouraging laboratories to contact them if they have problems or issues. Process to prepare package and forward whole volume samples: this was not an easy process. Each individual whole volume sample was prepared with an ampule. Desire to compare the data from the whole volume study to an ampule study.

- *? Should there be a difference in data quality between ampule and whole volume studies?*
  MC – they are equivalent and he would be somewhat surprised that a provider can use the acceptance protocols to meet the criteria because you are now using whole volume samples so the providers are now required to use similar methods as the laboratories to evaluate HSV.
  APG June study OG and TSS were an issue. TSS there was a homogeneity issue that they found after the study went out.
  MC - Whole volume projects are generally not used for regulatory purposes. Labs typically do better on ampule, less as well on whole volume and even less as well on double blinds. Risk of PT provider increases when you move to a whole volume sample. It is inherently more expensive to provide whole volume, shipping is much higher also. $17,000 vs. $3000-4000.

- PT Providers - Whole volume samples are generally provided on a program specific basis.

- Wibby – PT Provider becomes more of a part of the process by bringing the samples up to volume. This portion of the process is usually the laboratory's responsibility. Processes for HSV data determination and analysis have to be different because you have a whole volume instead of an ampule.

- *? By requiring whole volume is the level of uncertainty in the test increased?* You have added uncertainty, which can be the provider's ability to make homogenous samples. Argument that that this should reduce the variability because now one type of distilled water is used to bring the ampules up to volume. However the samples are now more unstable. However, the PT Providers have more stringent standards to meet.

<u>Troubleshooting</u>

- Questions that should be directed to OQA – payment, suspensions, sample replacements for breakage, extra sample volume (payment is required)
  This way we know what problems are occurring, if there are problems with a particular provider or laboratory.
  Sample make-up questions

- Questions that should be directed to providers – reporting, evaluations

- *? Stability studies from NYDOH for NJ – what is the process to get this data?* Would it be better for the PT providers to just send full data set to NJ rather than the labs requesting it and then forwarding them on. KJ stated that NY only runs a NELAC program, and there is no opportunity in the NELAC standards for an accrediting authority to request and review HSV data on a per state basis. Stability data is not

available to any AA. NY is overseen by NIST and they are not going to bring their state into oversight by another state accrediting authority.

- Requests that APG explain why the holding times on the whole volume samples are for the least holding time per analyte. They used the shortest holding time for all of the compounds in the ampule to ensure they get evaluated as quickly as possible, and to ensure that holding times for short term holding time parameters were met. Thought longer holding times for other analytes would be recognized without stating them.

- *? How do we compare whole volume to other PT Provider's ampule data?* They weren't compared to another provider but they were compared to whole volume samples.

- *? Where are complaints against a PT Provider directed?*
  RW - If it is a NIST analyte (old EPA analyte) you could contact NIST. Analytes not covered by NIST but are NELAC, you have to document the problem, document that you talked to the PT Provider and if unresolved it goes to the NELAP PT Board, until an oversight body is in place. Complaints should be addressed to the NELAP director in writing.

- DW Microbiology Debra Waller: For Membrane Filter verification, the tube media used must be incubated overnight to allow for degassing of dissolved gasses prior to the actual testing.

- *? Is there a source of free software for the labs to download to get homogeneity data?*
  There are websites available to provide this type of information. They will be included in the minutes.

----------Respectfully submitted:
Betty Jane Boros-Russo
Office of Quality Assurance